

the results of various MCEs. Those assumptions that yield the potential for more severe consequences, as opposed to assumptions that operational and safety controls will always perform as designed, will be used. The rule of reason will be applied to confine the MCE to realistic or believable occurrences.

(c) When considering an MCE, consider the redundancy of safety systems engineered into the facilities and the equipment used, depending on containment level required to make them as fail-safe as practical. The MCE for containment laboratories must be considered in terms of physical containment for both toxins and biological organisms. Therefore, both toxin and biological MCEs will be considered.

(d) Because aerosols of etiologic agents represent the most significant potential hazard for exposure of workers or the environment, a hazard analysis (to include MCE) of proposed BDP RDTE activities will be performed to determine the procedures, engineering controls, and facility design required to mitigate potential significant hazards.

#### **§ 626.13 Controls.**

(a) Personnel who are not needed to operate a BDP laboratory, will not be allowed to enter potentially hazardous areas.

(b) Written procedures to control access and ensure that personnel can be evacuated or protected from exposure may be used in place of absolute personnel exclusion.

#### **§ 626.14 Waivers and exemptions.**

(a) The goal of the biological defense safety program is strict adherence to safety standards and the elimination of all waivers and exemptions.

(b) Waiver authority. (1) The Chief of Staff, Army (CSA) is the controlling authority for granting waivers of biological defense safety standards. This authority is redelegated by this regulation to commanders of MACOMs and the commander of the USAMRDC.

(2) Waiver authority will not be sub-delegated.

(3) Commanders with waiver authority will—

(i) Ensure the existence of necessary and compelling reasons before granting waivers.

(ii) Grant waivers to standards for installations and activities within their areas of authority.

(c) Waiver requests: (1) Commanders of installations and activities will submit a request for waiver when compliance with these standards cannot be achieved. When such waivers affect on other commands, initiating activities will coordinate requests with those commands.

(2) Requests for waivers will contain the following information:

(i) Description of conditions. State the mission requirements and compelling reasons which make the waiver essential and the impact if not approved, and describe all affected sites or facilities and the quantity and type of BDP required.

(ii) The safety regulations, including specific safety requirements or conditions cited by paragraph, from which the waiver is requested, and the reasons for the waiver.

(iii) Specific time period for which the waiver is requested.

(iv) A hazard analysis which identifies actual and potential hazards which can result from the waived requirements or conditions.

(v) A risk assessment that provides information on the risk being assumed because of the waiver. The assessment will include those safety precautions and compensatory measures in force during the waiver period.

(vi) A waiver abatement plan to include milestones, resources, and actions planned to eliminate the need for the waiver.

(3) Requests for waivers will be forwarded through command channels to the MACOM or CG, USAMRDC, as appropriate, for approval. MACOM or USAMRDC safety officials will forward a copy of approved waivers to HQDA, DACS-SF, WASH DC 20310-0200. Copies of all waivers will be maintained at the installation and MACOM or USAMRDC Safety Offices for up to 3 years after the waiver is terminated.

(4) Time limitations: (i) Waivers are normally limited to 1 year or less, and will be considered rescinded after 1 year, unless reviewed. The activity or

installation commander forwarding a request for waiver will allow time to permit investigation, evaluation, and reply.

(ii) Waivers may be renewed each year by the commander originally granting the waiver for a waiver period not to exceed 5 years. Prior renewal, commanders will review the need for the waiver to ensure that circumstances requiring the waiver have not changed. Results of this review (and a progress report regarding milestones that have been completed) will be forwarded through command channels to the commander originally granting the waiver.

(iii) A request for amendment will be initiated when factors or circumstances requiring a change to the original waiver are identified.

(iv) When factors or circumstances prevent correction of the waiver condition within 5 years of the initial approval of the waiver, such condition becomes a candidate for an exemption.

(d) Exemptions. (1) Exemptions are relatively long-term exceptions to otherwise mandatory standards. Exemptions will be granted only under the following conditions:

(i) If corrective measures are impractical.

(ii) If impairment of the overall defense posture would result.

(iii) If positive programs to eliminate of the need for the exemption are being pursued.

(2) Exemptions can be approved only by the Secretary of the Army.

(i) Requests for exemptions will be sent through command channels to HQDA, DACS-SF, WASH DC 20310-0200.

(ii) Exemption requests will include the information required in paragraph(c)(2) of this section.

(iii) Copies of exemption requests will be maintained at the installation and MACOM or USAMRDC Safety Offices.

### Subpart C—BDP Contractors

#### § 626.15 Written procedures for contractor review.

The contracting agency will prepare written procedures for reviewing contractor capability to safely perform BDP work with etiologic agents. The

written procedures will describe the criteria and guidelines for preparing the facilities description, safety requirements, special procedures and techniques, inspection procedures, and MCE scenarios. These written procedures will be submitted to the contracting agency MACOM for review and approval.

#### § 626.16 Contracting agencies.

Contracting agencies, in coordination with their respective Command safety offices will monitor contractor performance in meeting safety requirements.

(a) The contracting agency will establish an inspection program and schedule for all BDP contractors who perform contract work with BL-3 or BL-4. Inspections will be conducted by safety and health personnel. The schedule will include, as a minimum, the following:

(1) A pre-award inspection on site, prior to contract award, for initial contracts for BDP work requiring BL-3 or BL-4 operations. If during a pre-award inspection, major corrective measures are required, a reinspection is required prior to the beginning of contract operations.

(2) A pre-award inspection of follow-on BL-3 and BL-4 contracts.

(3) A pre-operational inspection if a major change in procedures, facilities, or equipment is made after the pre-award survey.

(4) Annual inspection of BL-3 and semiannual inspection of BL-4 contractor facilities, equipment, and operations.

(b) Pre-award surveys and annual inspections of contractors performing work requiring BL-3 or BL-4 will be conducted by safety and health professionals trained in BDP operational safety requirements. Pre-award surveys and annual inspections of BL-1 and BL-2 contractors will be conducted by safety and health professionals or contracting agency representatives who are trained in biological safety inspection techniques. The Safety Inspection Checklist in DA Pam 385-69 will be used.

(c) The contracting agency will require each BDP contractor whose contract requires the use of etiologic